

### **REMARKS**

Claims 1-5 are currently pending in the application. Only claim 1 is in independent form.

The application is objected to because there is no abstract of the disclosure. An abstract on a separate sheet of paper is enclosed herewith, and reconsideration of the objection is respectfully requested.

Claims 1 and 4 are objected to for reciting non-elected inventions. In order to further prosecution, the claims have been amended to be limited to the elected inventions. Reconsideration of the objection is respectfully requested.

Claims 1-5 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the antibody made against the acetylcholinesterase fragment peptide of SEQ ID No: 1, to be used for identifying production of the AChE splice variant in the brains of mice, does not enable an antibody made against a variety of possible acetylcholinesterases for diagnosing central nervous system stress in animals or humans, or for identifying production of the AChE splice variant in animals other than mice. It is respectfully submitted that the claims have been amended to be limited to SEQ ID No: 1, thereby rendering the present rejection moot, and reconsideration of the rejection is respectfully requested.

Further, the Office Action states that the specification does not enable the use of the AChE-R antibody to diagnose "central nervous system stress" since central nervous system stress is poorly defined in the specification and may encompass a variety of neurological disorders. When reading the specification on page 1, lines 6-8, there is disclosed that, "the stressed CNS condition includes penetrants of high molecular weight substances through the blood brain barrier . . . ." Thus, "stressed humans" refers to patients in which an enhanced Omnipaque signal was detected by CT brain scans (as referred to on page 20). The definition of central

nervous system stress continues wherein it states, “. . . stress due to psychological, chemical and physical insults.” On page 2, lines 16-18 of the specification, there is disclosed that physical insults are defined as being preferably head injury, head trauma, or exposure to radiation, whereas chemical insults are defined as being preferably exposure to insecticide or nerve gas. With regard to the swim stress example, the specification refers to the swim stress as an example of psychological stress as mentioned on page 21, lines 24-25, (. . . mice were subjected to confined swim protocol for exerting acute psychological stress . . .”). Furthermore, the experiment involved swim stress in mice as a stress treatment, which is widely accepted and known to those of skill in the art as a model system that reflects universal responses of mammals in general to various stress responses. Based on the above, central nervous system stress is defined as a condition that results from any one of the above described insults and as such, is thoroughly defined within the specification as filed.

Further support for the definition of “central nervous system stress” can be found in other publications where there is disclosed that the switch from AChE-S to AChE-R, is indeed a reliable indication of CNS stress regardless of what triggered the condition. This has been demonstrated in mice following physical stress such as head injury (Shoham et al. 2000), chemical stress (exposure to organophosphates) (Kaufer, et al. 1999), immobilization stress (Nijholt et al. 2004), switch of day-to-night stress (Cohen et al. 2002), and in humans under neurological disease (Tomkims et al. 2002) and following LPS exposure (Cohen et al. 2003). Accordingly, there is sufficient support in the specification as filed for the use of central nervous system stress as recited in the claims. Reconsideration of the rejection is respectfully requested.

Claims 1-3 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over the Boschetti, et al. reference. In order to further prosecution, the limitations in claims 4 and 5 have been incorporated into independent claim 1 and as claims 4 and 5 were not part of the instant rejection, this claim amendment is sufficient to overcome the prior art and reconsideration of the rejection is respectfully requested.

Claims 1-5 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Office Action indicates that the phrase, "central nervous system stress" is indefinite because it is a conditional term that is poorly defined in the specification. When reading the specification on page 1, lines 6-8, there is disclosed that, "the stressed CNS condition includes penetrants of high molecular weight substances through the blood brain barrier . . . . "Thus, "stressed humans" refers to patients in which an enhanced Omnipaque signal was detected by CT brain scans (as referred to on page 20). The definition of central nervous system stress continues wherein it states, ". . . stress due to psychological, chemical and physical insults." On page 2, lines 16-18 of the specification, there is disclosed that physical insults are defined as being preferably head injury, head trauma, or exposure to radiation, whereas chemical insults are defined as being preferably exposure to insecticide or nerve gas. With regard to the swim stress example, the specification refers to the swim stress as an example of psychological stress as mentioned on page 21, lines 24-25, (. . . mice were subjected to confined swim protocol for exerting acute psychological stress . . ."). Furthermore, the experiment involved swim stress in mice as a stress treatment, which is widely accepted and known to those of skill in the art as a model system that reflects universal responses of mammals in general to various stress responses. Based on the above, central nervous system stress is defined as a condition that results from any one of the above described insults and as such, is thoroughly defined within the specification as filed. Accordingly, there is sufficient support in the specification as filed for the use of central nervous system stress as recited in the claims. Reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing



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features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Connie Herty